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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,940	11/26/2003	Sherry Leonard	VARD-07989	4237
23535 7590 03/12/2008 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105				
EXAMINER STANDLEY, STEVEN H				
ART UNIT 1649		PAPER NUMBER		
MAIL DATE 03/12/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/723,940

Applicant(s)

LEONARD ET AL.

Examiner

Steven H. Standley

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/26/27.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 6, 8, 26 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6, 8, 26, and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

RCE

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2006 has been entered.
2. Claims 1-2, 5-6, 8, 26, and 35-38 are under examination.

Rejections/Objections: withdrawn.

Claim Rejections - 35 USC § 112

3. Rejection of claims 26 and 35-38 under 35 USC § 112, 1st paragraph enablement, is withdrawn due to applicant's amendment. Specifically, applicant has included recitation of detection of the C to T mutation at position -86 of the promoter region.
4. Rejection of claims 1, and 5-7 under 35 USC § 112, 2nd paragraph, is withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 102

5. Rejection of claims 2-6, and 26-36 under 35 USC § 102(a), is withdrawn due to applicant's declaration.

Rejections/Objections: New and Maintained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The claimed invention is directed to non-statutory subject matter. Claims 1-2, 5-6, 8 26, and 35-38 are directed to non-statutory subject matter because they recite or depend from claims that recite, "correlating the presence of said at least one polymorphism with a predisposition to schizophrenia." In other words, the method is an experimental algorithm designed to identify further natural relationships between variants of the promoter and schizophrenia. This is an experiment that identifies a relationship between any unknown variant or variants of the promoter region and schizophrenia, which is a natural phenomena or law of nature and does not require practical application of such. The method does not require the diagnosis of schizophrenia from what is detected. Instead, it determines a natural correlation that either does or does not exist between any known or unknown variation and schizophrenia in a patient. In other words, the results are not concrete but are a method of identifying natural phenomena.

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Thus, the method as claimed would impermissibly cover every substantial practical application of, and thereby preempt all use of, an abstract idea, natural phenomenon, or law of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 5-6, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying individuals with increased likelihood of having schizophrenia comprising providing a nucleic acid from a human subject, detecting the presence of a -86 C to T substitution in relation to a start codon of said alpha 7 allele beginning at residue 270 of SEQ ID NO: 125, does not reasonably provide enablement for a method of identifying individuals predisposed to schizophrenia by "detecting the presence of at least one polymorphism within a core promoter region corresponding to SEQ ID NO: 125 of said alpha 7 allele wherein said at least one polymorphism contributes to reduced transcription. Furthermore, the specification does not reasonably provide enablement for the used of any of the other variants as indicators that a human subject is predisposed to schizophrenia. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is maintained from the prior office actions of 7/27/07 and 6/06/06. While some amendments by applicant have furthered prosecution, some are incompatible with the aim of the method.

The method of claim 1 recites "A method of identifying individuals predisposed to schizophrenia comprising," and then further recites detecting the presence of a generic polymorphism in the alpha-7 promoter region (which is not enabled as argued in prior actions; see 7/27/07 and 6/06/06), and finally by "providing a diagnosis of schizophrenia to said subject on the basis of...a physician review."

The method does not work because the relationship between a generic variant in the promoter region and schizophrenia is not known, and a physician cannot predict whether a patient is predisposed to schizophrenia, except when the C toT -86 variant is present. It is a well-known fact that physicians cannot predict that a person is predisposed to a disease, and in particular schizophrenia.

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Applicant says on page 6 of Remarks dated 9/26/07 that the examiner has indicated claims 7, 8, and 37 are allowable. However the examiner asserts that remaining claim 8 depended from claim 7 but has been amended to depend from claim 1. As amended the claim is not allowable.

Applicant argues on page 7 of Remarks dated 9/26/07 that the amendment to "and d) providing a diagnosis of schizophrenia to said subject based on the presence of at least one polymorphism and a physician interview" should obviate the enablement rejection. This is not found persuasive because the only predictor of a predisposition

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available to the physician is the presence of a (generic) variant in the promoter region of the alpha-7 gene. The examiner has already argued that applicant is not enabled for the scope of the claim. See prior actions 7/27/07 and 6/06/06.

Applicant should also note that the action of 7/27/07 states that reduced transcription bears no relationship itself with a predisposition for schizophrenia. Many of applicant's variants show reduced transcription, but only one is enriched in schizophrenia.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Stucker can be reached on **(571) 272-0911**.

The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

/Jeffrey Stucker/
Supervisory Patent Examiner, Art
Unit 1648

Steve Standley, Ph.D.
2/20/08